UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., and TEVA NEUROSCIENCE, INC., Defendants.	)	No. 20-cv-11548-NMG

THE UNITED STATES' RESPONSE TO TEVA'S OBJECTIONS TO THE MAGISTRATE JUDGE'S ORDER ON TEVA'S MOTION TO COMPEL INTERNAL HHS-OIG COMMUNICATIONS

The Court should overrule Teva's Objections (ECF No. 145) to Magistrate Judge Boal's Order denying Teva's Motion to Compel Internal HHS-OIG Communications (ECF No. 143). The Magistrate Judge properly found that Teva failed to establish a basis to support an *in camera* review of the documents it seeks, including for three independent reasons: (i) Teva failed to challenge the adequacy of a single attorney-client privilege designation on the government's privilege log, which covered all documents at issue; (ii) Teva failed to meet its burden to demonstrate that the internal HHS-OIG communications are relevant to a purported "good faith" defense; and (iii) Teva failed to show that the Court should override the deliberative process privilege, which also applied to all documents at issue. Nothing in Teva's Objections, which largely reiterate the same arguments that the Magistrate Judge properly considered and rejected, establishes that the Order is "clearly erroneous or . . . contrary to law." Fed. R. Civ. P. 72.

In addition to these grounds, each of which is a sufficient reason to overrule Teva's Objections, even if the Court were to find that Teva has identified an "interpretation" of the two

HHS-OIG guidance documents at issue,[1] that "interpretation" is objectively unreasonable for three reasons. First, the plain language of the 2005 Guidance directly contradicts Teva's supposed interpretation; second, Teva's purported interpretation is internally inconsistent; and third, Teva's interpretation contradicts black letter law on conspiracy and aiding and abetting. No internal HHS-OIG communications could possibly bolster the reasonableness of an "interpretation" that the Court can determine is objectively unreasonable as a matter of law.

For the reasons set forth below and in the United States' underlying briefing (ECF Nos. 99 & 115), the Court should overrule Teva's Objections.

I. BACKGROUND

The relevant background is set forth in detail in the government's underlying briefing and in the Magistrate Judge's Order. In short, the United States alleges in this case that Teva violated the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, and caused the submission of false claims to Medicare under the False Claims Act, 31 U.S.C. §§3729-33, by knowingly and willfully paying Medicare patients' copays for Copaxone, Teva's multiple sclerosis drug. Teva did so through and in conspiracy with a specialty pharmacy, Advanced Care Scripts, Inc. ("ACS"), and two pharmaceutical copay assistance foundations, Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF"). Teva was aware that the AKS barred it from paying, directly or indirectly, covertly or overtly, the copay obligations of Copaxone patients. In addition, Teva was aware of the 2005 and 2014 Guidance documents, which warned that copay assistance foundations should not "function as conduit[s] for payments by the pharmaceutical manufacturer

[1] HHS-OIG's 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees (the "2005 Guidance"), 70 Fed. Reg. 70623 (Nov. 22, 2005) and HHS-OIG's 2014 Supplemental Special Advisory Bulletin, Independent Charity Patient Assistance Programs (the "2014 Guidance"), 79 Fed. Reg. 31120 (May 30, 2014).

to patients," and that manufacturers should not "solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products." ECF No. 1 ¶ 66; ECF No. 33 at 12-13; 17-18. The 2005 Guidance further warned against "the *pharmaceutical manufacturer* [or] any affiliate of the *manufacturer* (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager) exert[ing] any direct or indirect influence or control over the charity or the subsidy program." 2005 Guidance at 70626. Teva therefore acted knowingly and willfully when, among other things, it conspired with ACS, CDF, and TAF to engage in that very conduct.

The long record of the government's attempt to resolve the present motion without court intervention is also set forth in its underlying briefing and the Magistrate Judge's Order. In short, through its incredibly overbroad initial document requests, Teva sought, among other things, all documents in HHS-OIG's possession concerning CDF or TAF over an eleven-year period and all documents concerning the 2005 and 2014 Guidance documents. The government objected to these requests as overbroad, unduly burdensome, vague, and beyond the scope of Fed. R. Civ. P. 26, because they sought irrelevant information that is protected by the attorney-client or deliberative process privileges. Notwithstanding these objections, and in an effort to resolve the requests, the United States produced to Teva all communications between HHS-OIG and CDF and TAF as part of their respective Advisory Opinion requests, as well as hundreds of pages of documents that had previously been produced to a third party in response to Freedom of Information Act ("FOIA") requests concerning the 2005 and 2014 Guidance documents. *See* ECF No. 99 at 5. The parties then engaged in months of correspondence, after which the parties

agreed that the government would further produce, or log as privileged, all internal HHS-OIG documents (including communications) relating to or concerning the 2005 or 2014 Guidance documents that were prepared or created within the twelve months preceding issuance of the applicable document. ECF No. 79-1 at 10; ECF No. 99 at 5. In accordance with that agreement, the government expended dozens of hours working with HHS-OIG to identify any additional, potentially-responsive documents, and finding none, created and served a privilege log that contained 212 entries. ECF No. 79-1 at 10. All 212 entries asserted both the attorney-client and deliberative process privileges. ECF No. 79-1 at 10.

In its original Motion to Compel, Teva noted, "to avoid any ambiguity," that it sought "full responses to Teva's Requests for Production Nos. 22, 23, 26, 28, and 29 . . . as originally drafted." ECF No. 108 at 4. It was only after briefing was complete, during oral argument before Magistrate Judge Boal and then in supplemental briefing submitted after that hearing, that Teva narrowed its request to an *in camera* review of 95 internal HHS-OIG documents "relating to or concerning the 2005 or 2014 OIG Bulletins that were prepared or created within the 12 months preceding issuance of the 2014 OIG Bulletin (May 30, 2014) and included within the Government's Sept. 27, 2022 privilege log." ECF No. 126 at 3. Magistrate Judge Boal issued an Order denying Teva's Motion on January 25, 2023. ECF No. 143. Teva filed its Objection on February 8, 2023. ECF No. 145.

II. LEGAL STANDARD

In reviewing objections, the court will only "modify or set aside any part of the order that is clearly erroneous or is contrary to law." Fed. R. Civ. P. 72(a). The "clearly erroneous" standard "requires the district judge to accept the factual findings and conclusions of the magistrate judge unless, after reviewing the entire record, the district judge has a 'strong

unyielding belief that a mistake has been made.'" *Ferring Pharm. Inc. v. Braintree Lab'ys, Inc.*, 168 F. Supp. 3d 355, 358-59 (D. Mass. 2016) (quoting *Green v. Cosby*, 160 F. Supp. 3d 431, 433 (D. Mass. 2016)). A "respect for this standard is important, given the pivotal role that magistrate judges play in overseeing the conduct of the sort of complex pretrial discovery typified by this case." *Gargiulo v. Baystate Health Inc.*, 279 F.R.D. 62, 64 (D. Mass. 2012). Pure questions of law are reviewed *de novo*. *Ferring Pharm.*, 168 F. Supp. 3d at 359. Even where the review is *de novo*, the district court "may be slow to reverse a magistrate's careful conclusions, thoughtfully reviewed." *Forcucci v. United States Fidelity and Guar. Co.*, 11 F.3d 1, 1 (1st Cir. 1993). Courts apply a sliding scale of review to mixed questions of law and fact. *Ferring Pharm.*, 168 F. Supp. 3d at 359.

The District Court may affirm the Order on any basis supported in the record. *Zee-Bar, Inc. v. Kaplan*, 162 F.R.D. 422, 425 (D.N.H. 1993) (citing *Acha v. United States*, 910 F.2d 28, 30 (1st Cir. 1990)); *see also City of New York v. Beretta U.S.A. Corp.*, No. 00-CV-3641 (JBW)(CLP), 2005 WL 1279183, at *1 (E.D.N.Y. May 26, 2005) (citing *Richardson v. Selsky*, 5 F.3d 616, 621 (2d Cir. 1993)).

III. ARGUMENT

A. Teva Raises No Objection To The Magistrate Judge's Ruling That Teva Failed To Challenge The Application Of The Attorney-Client Privilege

The Magistrate Judge found that Teva failed to raise any valid challenge to the United States' claim of attorney-client privilege over the documents at issue. ECF No. 143 at 8. Because Teva's Objections do not raise any argument against this ruling, which was an independent basis for denial of Teva's motion, the Court should overrule Teva's Objections.

Teva's Motion, as narrowed by Teva in its post-hearing submission, sought *in camera* review of a subset of documents listed on the United States' privilege log. ECF No. 143 at 5

(citing ECF No. 126 at 3). The United States asserted attorney-client privilege over each of the documents subject to the Motion (and in fact, over all documents on the log). *Id.*; *see also* ECF No. 99-5 at 69-91 (privilege log). In support of its claim of privilege, the United States also produced a declaration from Susan A. Edwards, Chief of the Industry Guidance Branch, Office of Counsel to the Inspector General ("OCIG") at the Department of Health and Human Services, attesting to the facts establishing privilege. ECF No. 99-1.

The Magistrate Judge found that Teva had not raised any valid challenge to the United States' claim of privilege. ECF No. 143 at 8. The Order found that "[w]ith respect to the attorney-client privilege, Teva does not challenge the adequacy of the privilege log or Ms. Edward's declaration. Rather, it simply argues that '[i]t is hard to believe that every single internal HHS-OIG document responsive to the parties' agreed terms involved the provision of legal advice and is protected from disclosure in full.'" ECF No. 143 at 8. The Magistrate Judge disagreed with Teva's threadbare argument that the privilege claim was "hard to believe," writing that "it is not surprising that a large of percentage of the documents responsive to the requests were privileged because Teva's requests center on OCIG—a legal department within HHS-OIG whose very function is to provide legal advice to the Inspector General. . . . Per Ms. Edwards, the requested documents were primarily drafted by IGB." ECF No. 143 at 8. In short, the Magistrate Judge found that Teva failed to raise any basis at all to rebut the United States' claim of privilege, and therefore failed to raise any basis for the Court to conduct an *in camera* review.

Teva's Objections do not challenge this aspect of the Order. Although the Objections contain a section purporting to challenge the ruling that Teva failed to show a basis for *in camera* review (*see* ECF No. 145 at 18, Section III.B), that section only discusses the balancing of

interests necessary to overcome the *deliberative process privilege*, and makes no mention of the United States' parallel assertion of the *attorney-client privilege*, which cannot be overcome with such a showing. In other words, Teva is not challenging any aspect of the government's assertion of attorney-client privilege, including the privilege log or the Edwards Declaration. Because Teva has failed to dispute an independent and dispositive basis for denying its Motion, the Court should overrule its Objections on that basis.

Regardless of Teva's failure to challenge the application of attorney-client privilege, the Magistrate Judge made no error of law or fact in denying *in camera* review of the documents. *In camera* review is at the discretion of the trial court, and is encouraged "[w]hen … the assertion of privilege is subject to legitimate dispute[.]" *In re Grand Jury Subpoena (Mr. S.)*, 662 F.3d 65, 70 (1st Cir. 2011). Here, the Magistrate Judge found no "legitimate dispute" regarding the assertion of privilege—only an unsupported claim that did not stand up to the barest scrutiny. The Court's decision to decline to undertake a burdensome privilege review of nearly one hundred documents—especially where the moving party (Teva) has provided no disputed issue to resolve—is in no way an abuse of discretion. *See, e.g., Cue, Inc. v. Gen. Motors LLC*, No. 13-cv-12647-IT, 2015 WL 4750844, at *9-10 (D. Mass. Aug. 10, 2015) (denying motion for in camera review where moving party provided "no reason to second guess any of the information set forth in [the] privilege log" and "has not cited any authority that would justify a review based solely on a party's need to uncover additional evidence").

B. The Magistrate Judge Correctly Found That Internal HHS-OIG Documents Are Not Relevant

1. Teva has not identified any ambiguity in the 2005 Guidance, or any interpretation that does not contradict the plain terms of the Guidance

The Magistrate Judge found that Teva failed to articulate how internal HHS-OIG documents would be relevant to its "good faith interpretation" defense. ECF No. 143 at 6-7.

That finding was correct, and certainly not clearly erroneous or contrary to law. Fed. R. Civ. P. 72(a). Contrary to Teva's Objections, the Magistrate Judge applied the proper scope of discovery and relevance standard under Federal Rule of Civil Procedure 26. *Id.* at 6.

As the Magistrate Judge correctly pointed out, Teva "has not identified any ambiguities or any interpretation of the guidance documents, the AKS or the FCA that Teva allegedly relied upon in good faith." *Id.* at 7. Instead, Teva merely points to statements from Teva employees, such as Patricia Glover (a former compliance officer), that (i) "the 2005 Guidance focused on the charity's intent, not the donor's intent," and (ii) that "while receiving data from a charity may be impermissible under the 2005 Guidance, receiving data from a patient support hub like ACS was different and permissible . . . ." ECF No. 145 at 4. This does not identify any ambiguity in the Guidance documents. Nor do the statements actually interpret *any* text from the Guidance documents themselves—the statements accordingly amount to little more than unfounded and general claims that Teva's conduct was legal, and are not an "interpretation" on which a good faith defense could be based.

Teva's statements also are inconsistent with the plain terms of the Guidance. *See, e.g., United States ex rel. Martino-Fleming v. South Bay Mental Health Ctrs.*, 540 F. Supp. 3d 103, 122-124 (D. Mass. 2021) (rejecting FCA defendant's purportedly objectively reasonable interpretations as unreasonable as a matter of law where they are "contradicted by the plain language of the regulations" or "[do] not square with the requirements set forth" in regulations). With respect to (i), Teva claims that the 2005 guidance "focused on the charity's intent." ECF No. 145 at 4. However, the Guidance discussed several different types of patient assistance programs, including those sponsored by pharmaceutical manufacturers and those operated by

independent charities.[2] With regard to the latter, the Guidance specifically warned against certain conduct by manufacturer donors. *See* 2005 Guidance at 70626 ("the *pharmaceutical manufacturer does not solicit or receive* data from the charity that would facilitate the *manufacturer* in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products") (emphases added). The guidance also expressly addressed manufacturer *conduct*, not *intent*. *Id*.[3] Finally, even if Teva were right that the 2005 Guidance "focused" on charities and their intents, Teva fails to identify how any "focus" of the Guidance creates a defense for Teva. Teva does not argue, for example, that the 2005 Guidance *exclusively* spoke to the charities or their intents.

With respect to (ii), there is no language in the Guidance (and Teva has pointed to no such language) that, as Teva claims, states or even implies that Teva might permissibly use a contracted third party (whether a hub or otherwise) to receive product-specific data.[4] As discussed below, the 2005 Guidance expressly warns against this by stating that "[n]either the *pharmaceutical manufacturer* nor any affiliate of the *manufacturer* (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) exerts any direct or indirect

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[2] *See* 2005 Guidance at 70625 (section titled "Pharmaceutical Manufacturer PAPs") and 70628 (section titled "Transitioning From Existing Pharmaceutical Manufacturer PAPs").

[3] That the 2005 Guidance does not itself focus on intent is no accident. It is the AKS, not the 2005 Guidance, that describes the prohibited intent. 42 U.S.C. § 1320a-7b(b)(2) ("Whoever knowingly and willfully offers or pays any remuneration . . . to any person to induce such person . . ."). The 2005 Guidance itself states that a "determination regarding whether a particular arrangement violates the [AKS] requires a case-by-case evaluation of all the relevant facts and circumstances, *including the intent of the parties*." 2005 Guidance at 70625.

[4] Even if Teva were right that the Guidance did not prohibit it from receiving data from ACS, that would hardly end the matter, because Teva's conduct was inconsistent with multiple other portions of the Guidance.

influence or control over the charity or the subsidy program." *See infra* at III.b.3.1. And, to the extent Teva claims that the 2005 Guidance was ambiguous because it did not specifically note that manufacturers should not receive product-specific data from a hub, Teva's argument amounts to a claim that the 2005 Guidance was ambiguous because it did not list all the ways in which Teva could either conspire with or improperly use a third party (here, ACS) to do that which Teva already knew was problematic (receive data from which it could correlate its patients with Teva's payments to the foundation). This is not an "interpretation" of guidance upon which a good-faith defense could be made. Accordingly, Teva has not identified any issue with the 2005 Guidance, as the Magistrate Judge correctly found. ECF No. 143 at 7.

2. Because Teva has not identified any ambiguity in, or any textual interpretation of, the 2005 Guidance, it has failed to demonstrate the relevance of its request for HHS-OIG documents

Having failed to identify any aspect of the 2005 Guidance that is problematic, the Magistrate Judge correctly found that Teva has no basis upon which to ground its request for (privileged) HHS-OIG documents. ECF No. 143 at 7. The Magistrate Judge did not hold, as Teva would have it, that Teva must "proffer[] evidence at the discovery stage," ECF No. 145 at 12. Rather, Teva simply must articulate the relevance of the HHS-OIG documents to its purported good faith defense. ECF No. 143 at 7 n. 2.[5] The Magistrate Judge was correct to find that it had not done so, and certainly that finding was not clearly erroneous or contrary to law.[6]

[5] As the Magistrate Judge said, "[c]ontrary to Teva's suggestion, the requirement for a foundation for its good faith defense does not require it to proffer evidence to support its discovery request. Rather this Court finds that Teva must articulate with specificity the basis of its defense and that it has failed to do so." ECF No. 143 at 7 n. 2.

[6] While Teva asserts that the Order is "internal[ly] inconsistent[] because the Magistrate Judge noted that Teva could "seek . . . discovery regarding other drug manufacturers' interpretation of the SABs," (ECF No. 108 at 15) the United States consistently has taken the position that such documents from other manufacturers would be irrelevant. *See, e.g.,* ECF No. 99 at 18.

In finding that Teva had failed to identify any issues with the 2005 Guidance, the Magistrate Judge cited this Court's decision in *United States v. Facteau*, No. 15-cr-10076-ADB, 2015 WL 6509120, at *4 (D. Mass. Oct. 28, 2015) (citing *United States v. Lachman ("Lachman II")*, 521 F.3d 12, 19 (1st Cir. 2008)).[7] As the Magistrate Judge pointed out in her Order, ECF No. 143 at 6-7, that decision held that a defendant may use "non-public agency statements . . . to support a good faith defense where there is some evidence that the defendant acted in the good faith belief that his conduct was lawful, *and that the agency's internal analysis bolsters the reasonableness of the defendant's interpretation of the law.*" In *Facteau*, the Court found that the defendant failed to articulate how the FDA's internal discussions were relevant to the defendants' interpretation of the statute at issue. ECF No. 143 at 7 (citing *Facteau*, 2015 WL 6509120 at *4). Precisely so here—Teva has not explained how HHS-OIG's internal discussions are at all relevant to any Teva witness's "interpretation" of the 2005 Guidance.[8]

Moreover, without more, such documents would not implicate the same attorney-client or deliberative process privilege concerns as the ones that Teva seeks here.

[7] In addition to citing *Facteau*, the Magistrate Judge cited *Lachman II* in support of its finding that Teva must provide adequate foundation for its purported good faith defense. Although Teva claims the Magistrate Judge's reliance on *Lachman II* is error because *Lachman II* assessed the defendant's request for the withheld materials post-verdict, the Magistrate Judge's analysis, based on among other things the holding in *Facteau*, is simply that Teva needs to articulate some relevance to its request for agency documents, and it has not done so here. And, as in this case, the *Facteau* opinion analyzed similar issues at the discovery stage.

[8] By contrast, in *United States v. Berkeley Heartlab*, No. 11-1593, 2017 WL 2633500, at *4 (D.S.C. June 19, 2017), a non-binding out-of-circuit decision, the defendant specifically identified its belief that there were "communications between employees at the Department of Justice that reflect as of January 2014, the Department of Justice did not even 'know' whether the payment of P&H fees by laboratories was unlawful." While the United States maintains that such communications would be irrelevant, Teva has offered *no* explanation for how any HHS-OIG communications would be relevant to its purported interpretation. Moreover, as discussed in further detail below, Teva's interpretation was objectively unreasonable, and no internal agency communications could accordingly bolster its reasonableness.

3. Teva's purported interpretation is objectively unreasonable

As an independent basis for overruling Teva's Objection, Teva's purported good faith interpretation of the 2005 Guidance is objectively unreasonable, and no internal agency discussion could "bolster[] the reasonableness of the defendant's interpretation of the law." *Facteau*, 2015 WL 6509120 at *4. As described above, in its Objections, Teva asserts that its good faith interpretation was that "(1) the 2005 Guidance focused on the charity's intent, not the donor's intent; (2) while receiving data from a charity may be impermissible under the 2005 Guidance, receiving data from a patient support hub like ACS was different and permissible . . . .". ECF No. 145 at 4. Teva's good faith interpretation is unreasonable because (i) the plain language of the 2005 Guidance directly contradicts Teva's supposed interpretation, (ii) it is internally inconsistent, and (iii) it disregards black letter law on conspiracy and aiding and abetting.

i. The 2005 Guidance Directly Contradicts Teva's Interpretation

Teva's contention that it interpreted the 2005 Guidance to "focus[] on the charity's intent, not the donor's intent" is objectively unreasonable. The 2005 Guidance states that "[u]nder a properly structured program, donations from a pharmaceutical manufacturer to an independent, *bona fide* charity that provides cost-sharing subsidies for Part D drugs should raise few, if any, anti-kickback statute concerns so long as," and then lists five separate conditions, each of which must be followed. 2005 Guidance at 70626. Two of those conditions plainly warn *pharmaceutical manufacturers* (*i.e.*, the "donors") against taking certain types of *conduct*. The first provision states that "[n]either the *pharmaceutical manufacturer* nor any affiliate of the *manufacturer* (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) exerts any direct or indirect influence or control over the charity or the subsidy

program." *Id.* (emphasis added). Another states that the "*pharmaceutical manufacturer* does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products." *Id.* (emphasis added). The 2005 Guidance directly contradicts Teva's argument that the Guidance does not focus on the manufacturer; plainly, in those two sections it does focus on the donors (and those sections focus on conduct, not intent). *See* ECF No. 33 at 17-18 ("Teva's reliance on that guidance is unavailing. . . . [The 2005 Guidance] list[s] several safeguards . . . including that the manufacturer may not solicit or receive data from the charity to correlate its donations with the payments to be used on its products. The guidance also cautions against the use of such charities 'as a conduit' for payments to patients.") (internal citations omitted).

ii. Teva's Interpretation is Internally Inconsistent, and Therefore Objectively Unreasonable

Teva's supposed good faith interpretation is internally inconsistent. On the one hand, Teva claims that the 2005 Guidance "focused on the charity's intent, not the donor's intent," by which Teva apparently means that the 2005 Guidance did not apply to Teva. ECF No. 145 at 4. On the other hand, however, Teva contends that "while receiving data from a charity may be impermissible under the 2005 Guidance, receiving data from a patient support hub like ACS was different and permissible." *Id*. If the 2005 Guidance does not apply to donors, (under Teva's interpretation that the Guidance "focused" on the charity), then it could not have *affirmatively permitted* Teva to receive data from entities like ACS. Of course, the 2005 Guidance does not state that pharmaceutical-manufacturers may receive manufacturer-specific information from patient support hubs; tellingly, Teva can point to no such language in the Guidance. The plain language of the 2005 Guidance nowhere blesses Teva's supposed good faith interpretation that it

was permitted to receive product-specific data from ACS, which only serves to highlight that Teva seeks to manufacture a good faith interpretation *now*, in litigation.[9]

iii. Teva's Purported Good Faith Interpretation Contradicts the Law of Conspiracy and Aiding and Abetting

Teva's "understanding" that "while receiving data from a charity may be impermissible under the 2005 Guidance, receiving data from a patient support hub like ACS was different and permissible" also is objectively unreasonable because it is contrary to black letter law concerning conspiracy and aiding and abetting, as well as the plain language of the 2005 Guidance concerning manufacturers acting through third parties. *Id*. The government alleges not only that Teva improperly *used* ACS to do that which Teva knew was illegal, but also that Teva *conspired* with ACS to do the same. ECF No. 1 at ¶¶ 4, 5, 50-53, 56-57, 76-78, 82-90, 130. Under Teva's reading of the 2005 Guidance, any defendant could engage in conduct contrary to the plain language and intent of a guidance document simply by conspiring with or aiding and abetting a third-party engaged in that conduct. Under Teva's reading, such a conspiracy would reflect an "ambiguity" in the Guidance, creating a "good faith" defense. Teva cites no authority in support of this position. *United States ex rel. Kuzma v. Northern Arizona Healthcare Corporation*, 2021 WL 75827, at *7 (D. Ariz. Jan. 8, 2021) (finding a defendant's "narrow reading" of a regulation objectively unreasonable where it was "contrary to the clear intent of the statute and regulations" and that the court "cannot conclude that the law permits so easy an end-run around its intent.") (citation omitted).

[9] Indeed, Denise Lynch, Teva's Vice President of Patient Services who supervised Teva's Shared Solutions and Teva's copay assistance program, testified that she believed the Guidance *did* apply to Teva. *See* ECF No. 108-1 at 2: ("Q: Okay. So that's the number of Copaxone patients at ACS who were receiving assistance from The Assistance Fund at that time? A: Right. Q: Why didn't you ask The Assistance Fund for that information? [Objection]. A: Because I wasn't supposed to. Q: Why weren't you supposed to? A: Because of the regulations.").

Moreover, the 2005 Guidance cautions against any "manufacturer [or] *any affiliate of the manufacturer (including, without limitation . . . any . . . agent*" exerting any "direct or indirect influence or control over the charity or the subsidy program." 2005 Guidance at 70626 (emphases added). Teva cannot plausibly assert that ACS was not Teva's "agent" or "affiliate" within the meaning of the 2005 Guidance; consequently, Teva's "understanding" with respect to the propriety of receiving data from CDF or TAF through ACS plainly is inconsistent with this language. *Martino-Fleming*, 540 F.Supp.3d at 124 (D. Mass 2021) (rejecting purportedly reasonable interpretation where "[t]he Defendants' interpretation is contradicted by the plain language of the regulations.").

And in any event, it is well-settled law that a statute prohibiting certain conduct *need not* also explicitly prohibit conspiracy to engage in that conduct (or the related offense of aiding and abetting that conduct), and the absence of any such explicit prohibition does not render that statute ambiguous with respect to conspiracy. Where conduct is prohibited, conspiracy to commit that conduct (or to aid and abet it) is also prohibited. *See United States v. Herrera*, 584 F.2d 1137, 1150 (2d Cir. 1978) ("Since one can violate a criminal statute merely by engaging in the forbidden conduct, a conspiracy to commit that offense is nothing more than an agreement to engage in the prohibited conduct."); *United States v. Bravo-Fernandez*, 756 F. Supp. 2d 184, 193 (D.P.R. 2010) (it is "well-settled law of the First Circuit that 'the government may rely on an aiding and abetting theory, although the indictment neither alleges nor adverts to it.'" (*quoting United States v. Sanchez*, 917 F.2d 607, 611 (1st Cir. 1990)); *United States v. Footman*, 215 F.3d 145, 153-4 (1st Cir. 2000) (finding that an aiding and abetting charge is implicit in all indictments for substantive offenses). Teva's assertion that it could conspire with ACS (or that ACS could aid and abet Teva) to obtain Teva-specific data that Teva has acknowledged it could

not otherwise receive directly from CDF or TAF, and that this was "permissible" (or at least vague and ambiguous) under the 2005 Guidance, is objectively unreasonable.

C. In Holding That Teva Failed To Overcome The Deliberative Process Privilege, The Magistrate Judge Was Not Required To First View All Ninety-Five Documents *In Camera*

The United States asserted the deliberative process privilege—in addition to attorney-client privilege—over each of the documents at issue. *See* ECF No. 143 at 8; *see also* ECF No. 99 at 15. In its motion, Teva did not challenge the application of the deliberative process privilege to the documents at issue; rather, Teva argued that the privilege should be overcome by Teva's purported need for the documents. *Id.* The Magistrate Judge conducted the requisite balancing test—analyzing each of the five non-exhaustive factors specified in First Circuit caselaw—and held that based on the balancing of interests, "Teva has not shown that the deliberative process should be overcome in this case or that this Court should perform an *in camera* review of the subject documents." *Id.* at 10.

Teva's sole objection to this ruling is that the Magistrate Judge failed to conduct an *in camera* review of each and every document in dispute. *See* ECF No. 145 at 18-19. According to Teva, the law required the Magistrate Judge to order the United States to submit all disputed documents "for an individualized review," and that the Magistrate Judge's failure to do so amounted to an error of law. *Id.*

Binding First Circuit caselaw forecloses Teva's argument. *Town of Winthrop v. F.A.A.*, 328 F. App'x 1, *5 (1st Cir. 2009) (in reviewing privilege claims by agency in FOIA case, including claims of deliberative process, "the district court has the option, but not the obligation, to review the underlying documents in camera" and "is vested with the *discretionary* authority to review documents in camera" (emphasis added)); *see also Williams v. City of Boston,* 213 F.R.D.

99, 100 (D. Mass. 2003) (in determining whether deliberative process privilege is overcome, courts must balance conflicting interests "on a case-by-case"—not document-by-document—basis) (*quoting Gomez v. City of Nashua*, 126 F.R.D. 432, 434 (D.N.H. 1989)). Were the rule otherwise, any party could force any judge to review hundreds or thousands of disputed documents simply by arguing that the party's need for the documents outweighs the deliberative process privilege.

Looking past this binding precedent, Teva argues that *Kerr v. U.S. Dist. Court for Northern Dist. Of California*, 426 U.S. 394 (1976), which was quoted in *In re Pharm. Indus. Average Wholesale Price Litig.*, 254 F.R.D. 35, 40 (D. Mass. 2008), mandates *in camera* review. *See* ECF No. 145 at 19. But *Kerr* stands for no such rule—and in fact undercuts Teva's argument. In *Kerr*, the petitioner sought to overturn two discovery orders through a writ of mandamus. 426 U.S. at 395-396. The Supreme Court's inquiry centered on whether there existed, short of mandamus, "other adequate means to attain the relief [petitioner] desires." *Id*. at 403. The Court found that "other adequate means" existed because the petitioner had "the opportunity to apply for and, upon proper application, receive, *in camera* review" by the district court. *Id.* at 406. The Court noted in dicta that based on the facts of that particular case (which included considerations as serious as "the unwarranted disclosure and consequent drying up of confidential sources"), *in camera* review would be "eminently worthwhile" and "useful." *Id.* at 405. But such language underscores the fact that such review is *never* mandatory.

CONCLUSION

For the foregoing reasons, the Court should overrule Teva's objections to the Magistrate Judge's Order.

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Respectfully submitted,

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